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Subject: MTCA Rule Amendment

The Department of Ecology is planning to amend the Model Toxics Control Act (MTCA) Cleanup Regulation (WAC 173-340) to clarify the policy and procedures for establishing cleanup levels for mixtures of polychlorinated dibenzo-p-dioxins/polychlorinated dibenzofurans (dioxins/furans), polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

We have concluded that rule revisions are necessary to clarify previous rule interpretations and policy decisions. As background, the Environmental Protection Agency (EPA) has established a methodology for evaluating dioxin and furans using Toxicity Equivalency Factors (TEFs). The current MTCA Cleanup Regulation specifies that cleanup proponents may use the EPA methodology when establishing cleanup levels for mixtures of dioxin/furans. After publishing the rule amendments, we prepared guidance materials describing how the EPA methodology should be used to establish cleanup levels. A recent lawsuit challenged our application of the guidance. The lawsuit identified an ambiguity in the state's cleanup standards in terms of their application to mixtures of dioxins and furans and the use of the TEF methodology. Similar interpretation issues may exist for PAH and PCB mixtures. We have concluded that amending the rule to clarify key policy decisions is preferable to repeatedly resolving this issue on a site-specific basis.

We have established a schedule for amending the rule by the end of 2006. During the summer months, we will be preparing draft rule language and performing analyses required under the State Environmental Policy Act, the Administrative Procedures Act and the Regulatory Fairness Act. An early draft of the rule amendments is attached to this e-mail. Interested persons may submit comments on the draft rule language on or before July 28, 2006. We will review those comments as we prepare the proposed rule amendments that will be distributed for formal public comment at the end of the summer.

The formal comment period will start when we publish the proposed rule amendments in the State Register. As noted above, we plan to start the formal public comment period in late August or early September. Public hearings will be held in September. We will then review the public comments and make final determinations on the rule amendment. We plan to

complete the rulemaking process and adopt the final rule amendments by the end of December 2006.

Attached is an early draft of these proposed amendments. Comments on this proposed draft rule may be submitted on or before July 28, 2006.

If you have comments or questions on the draft rule language included in this paper, please contact:

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Proposed Amendments to the MTCA Cleanup Regulation Addressing Policies and Procedures for Certain Types of Chemical Mixtures

Overview

Ecology has initiated a rulemaking process to amend the Model Toxics Control Act (MTCA) Cleanup Regulation (Chapter 173-340 WAC). The purpose of the rulemaking is to clarify the policies and procedures for establishing cleanup levels for mixtures of polychlorinated dibenzo-p-dioxins/polychlorinated dibenzofurans (dioxins/furans), polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

- **Reasons for the Rulemaking:** Ecology has concluded that rule revisions are necessary to clarify previous rule interpretations and policy decisions. As background, the Environmental Protection Agency (EPA) has established a methodology for evaluating dioxin and furans using Toxicity Equivalency Factors (TEFs). The current MTCA Cleanup Regulation specifies that cleanup proponents may use the EPA methodology when establishing cleanup levels for mixtures of dioxin/furans. After publishing the rule amendments, Ecology prepared guidance materials describing how the EPA methodology should be used to establish cleanup levels. In November 2005, the Rayonier Corporation filed a lawsuit challenging Ecology's application of the guidance to the cleanup of a former pulp mill site in Port Angeles. The lawsuit identified an ambiguity in the state's cleanup standards in terms of their application to mixtures of dioxins and furans and the use of the TEF methodology. Similar interpretation issues may exist for PAH and PCB mixtures. Ecology has concluded that amending the rule to clarify key policy decisions is preferable to repeatedly resolving this issue on a site-specific basis.
- **Rulemaking Timeline:** Ecology has established a schedule for amending the rule by the end of 2006. Ecology filed a proposal statement of inquiry (CR-101) with the Office of the Code Reviser on June 7, 2006. During the summer months, Ecology will be preparing draft rule language and performing analyses required under the State Environmental Policy Act, the Administrative Procedures Act and the Regulatory Fairness Act. The Department plans to publish the proposed rule amendments for public review and comment by the end of August with public hearings being held in September. Ecology will then review the public comments and make final determinations on the rule amendment. Ecology plans to complete the rulemaking process and adopt the final rule amendments by the end of December 2006.
- **For Additional Information/to Submit Comments:** Ecology has prepared draft rule revisions that are designed to clarify the policies and procedures for establishing cleanup levels for mixtures of dioxins/furans, PAHs and PCBs. **Comments may be submitted on the draft rule on or before July 28, 2006.** If you have comments or questions on the draft rule language included in this paper, please contact Pete Kmet, Department of Ecology, Toxics Cleanup Program, P.O. Box 47600, Olympia, WA 98504-7600, e-mail pkme461@ecy.wa.gov, phone (360) 407-7199, fax (360) 407-7154. General information on the rulemaking process can also be obtained by contacting Dan Koroma, Department of Ecology, Toxics Cleanup Program, P.O. Box 47600, Olympia, WA 98504-7600, e-mail dkor461@ecy.wa.gov, phone (360) 407-7187, fax (360) 407-7154.

Draft Rule Revisions – Dioxins/Furans Mixtures (WAC 173-340-708(8)(d))

Ecology has identified several rule revisions that are intended to clarify the policies and procedures for establishing cleanup levels for mixtures of polychlorinated dibenzo-p-dioxins/polychlorinated dibenzofurans, including the following:

- New language to clarify that mixtures of dioxins and furans will be considered a single hazardous substance for calculating excess cancer risk and determining compliance with cleanup levels and remediation levels. This means a 1×10^{-6} cancer risk is applied to the mixture under Method B and a 1×10^{-5} cancer risk is applied to the mixture under Method C.
- Proposed revisions to update the rule to incorporate the most recent TEFs for dioxins/furans recommended by the World Health Organization. The updated TEF values are included in a new table (Table 708-1).
- A description of the procedures for using the TEF methodology for purposes of calculating cancer risk and/or evaluating compliance with cleanup levels and remediation levels.

The specific current proposed rule revisions to WAC 173-340-708(8)(d) are as follows:

~~(d) When assessing the potential carcinogenic risk of mixtures of chlorinated dibenzo-p-dioxins (CDD), and chlorinated dibenzofurans (CDF), either of the following methods shall be used unless the department determines that there is clear and convincing scientific data which demonstrates that the use of these methods is inappropriate:~~ The following procedures shall be used when calculating excess cancer risk and determining compliance with cleanup levels and remediation levels for mixtures of chlorinated dibenzo-p-dioxins and/or chlorinated dibenzofurans:

(i) Mixtures of chlorinated dibenzo-p-dioxins or chlorinated dibenzofurans or both together shall be considered a single hazardous substance.

(ii) The total toxic equivalent concentration is a measure of the toxicity of a mixture of chlorinated dibenzo-p-dioxins and/or chlorinated dibenzofurans. The total toxic equivalent concentration may be calculated using either of the following methods unless the department determines that there is clear and convincing scientific data which demonstrates that the use of these methods is inappropriate:

~~(A)~~ (A) The entire mixture is assumed to be as toxic as 2, 3, 7, 8 tetrachloro dibenzo-p-dioxin (2,3,7,8 TCDD), CDD or 2, 3, 7, 8-CDF, as applicable; or

~~(B)~~ (B) The toxicity equivalency factors in table 708-1 are used to convert the mixture to a total toxic equivalent concentration of 2,3,7,8 TCDD using the following process: and methodology described in: EPA, 1989. "Interim procedures for estimating risks associated with exposure to mixtures of chlorinated dibenzo-p-dioxins and dibenzofurans (CDDs and CDFs) and 1989 update", USEPA, Risk Assessment Forum, Washington, D.C., publication number EPA/625/3-89/016.

(I) Analyze a sample of the mixture or a sample from the medium of concern to determine the concentration of the seventeen congeners listed in Table 708-1;

(II) Multiply each congener concentration in the sample by its corresponding toxicity equivalency factor in Table 708-1 to obtain a toxic equivalent concentration of 2,3,7,8 TCDD for that congener; and,

(III) Add the toxic equivalent concentrations of all of the congeners to obtain a total toxic equivalent concentration of 2,3,7,8 TCDD for that sample.

(iii) The total toxic equivalent concentration derived under WAC 173-340-708(8)(d)(ii)(A) or (B), and the carcinogenic potency factor for 2,3,7,8 TCDD provided for

under WAC 173-340-708(a), shall be used to calculate excess cancer risk and determine compliance with cleanup levels and remediation levels.

WAC 173-340-900 includes the following new table:

Table 708-1 (*New Table*)
Toxicity Equivalency Factors for Chlorinated dibenzo-p-dioxins (CDD),
Chlorinated Dibenzofurans (CDF) and Dioxin-Like Polychlorinated Biphenols (PCBs)

Hazardous Substance	TEF (unitless) (1)
<u>Dioxin Cogeners</u>	
2,3,7,8-TCDD	1
1, 2,3,7,8-PeCDD	1
1, 2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
1,2,3,4,6,7,8,9-OCDD	0.0001
<u>Furan Cogeners</u>	
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8- HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9- HpCDF	0.01
1,2,3,4,6,7,8,9-OCDF	0.0001
<u>Dioxin-Like PCBs</u>	
3,3',4,4'-TCB	0.0001
3,4,4',5-TCB	0.0001
2,3,3',4,4'-PeCB	0.0001
2,3,4,4',5-PeCB	0.0005
2,3,4,4',5-PeCB	0.0001
2,3,4,4',5-PeCB	0.0001
3,3',4,4',5- PeCB	0.1
2,3,3',4,4',5-HxCB	0.0005
2,3,3',4,4',5-HxCB	0.0005
2,3,4,4',5,5'- HxCB	0.00001
3,3',4,4',5,5'- HxCB	0.01
2,2',3,3',4,4',5-HpCB	No value
2,2',3,4,4',5,5'-HpCB	No value
2,3,3',4,4',5,5'-HpCB	0.0001

(1) Source: Van den Berg, M; Birnbaum, L; Bosveld, ATC; et al. (1998) Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Health Perspect 106(12):775-792.

Draft Rule Revisions – PAH Mixtures (WAC 173-340-708(8)(e))

Ecology has identified several rule revisions that are intended to clarify the policies and procedures for establishing cleanup levels for mixtures of polycyclic aromatic hydrocarbons (PAHs), including the following:

- New language that is intended to clarify that mixtures of carcinogenic PAHs will be considered a single hazardous substance for calculating excess cancer risk and determining compliance with cleanup levels and remediation levels. This means a 1×10^{-6} cancer risk is applied to the mixture under Method B and a 1×10^{-5} cancer risk is applied to the mixture under Method C.
- Proposed revisions to update the rule to incorporate the most recent TEFs for carcinogenic PAHs developed by the California Environmental Protection Agency. The updated TEF values are included in a new table (Table 708-2).
- A description of the procedures for using the TEF methodology for purposes of calculating and/or evaluating compliance with cleanup levels and remediation levels.
- Retains the current requirement that, at a minimum, the seven PAH compounds identified in the current definition of “PAHs carcinogenic” be included in the analysis when using the TEF approach to characterize PAH mixtures.

The specific current proposed rule revisions to WAC 173-340-708(8)(e) are as follows:

~~(e) When assessing the potential carcinogenic risk of mixtures of polycyclic aromatic hydrocarbons either of the following methods shall be used unless the department determines that there is clear and convincing scientific data which demonstrates that the use of these methods is inappropriate: The following procedures shall be used when calculating excess cancer risk and determining compliance with cleanup levels and remediation levels for mixtures of carcinogenic polycyclic aromatic hydrocarbons (carcinogenic PAHs):~~

~~(i) Mixtures of carcinogenic PAHs shall be considered a single hazardous substance.~~

~~(ii) The total toxic equivalent concentration is a measure of the toxicity of a mixture of carcinogenic PAHs. The total toxic equivalent concentration may be calculated using either of the following methods unless the department determines that there is clear and convincing scientific data which demonstrates that the use of these methods is inappropriate:~~

~~(i)(A) The entire mixture is assumed to be as toxic as benzo(a)pyrene; or~~

~~(ii)(B) The toxicity equivalency factors in table 708-2 are used to convert the mixture to a total toxic equivalent concentration of benzo(a)pyrene using the following process: and methodology described in "CalEPA. 1994. Benzo(a)pyrene as a toxic air contaminant. Part B: Health Assessment." Published by the Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Berkeley, CA.~~

~~(I) Analyze a sample of the mixture or a sample from the medium of concern to determine the concentration of each of the carcinogenic PAHs listed in Table 708-2;~~

~~(II) Multiply each carcinogenic PAH concentration in the sample by its corresponding toxicity equivalency factor in Table 708-2 to obtain a toxic equivalent concentration of benzo(a)pyrene for that carcinogenic PAH; and,~~

~~(III) Add the toxic equivalent concentrations of all of the carcinogenic PAHs to obtain a total toxic equivalent concentration of benzo(a)pyrene for that sample.~~

~~(iii) The total toxic equivalent concentration of benzo(a)pyrene derived under WAC 173-340-708(8)(e)(ii)(A) & (B), and the carcinogenic potency factor for benzo(a)pyrene provided~~

for under WAC 173-340-708(a), shall be used to calculate excess cancer risk and determine compliance with cleanup levels and remediation levels.

(iii) When using ~~this methodology~~ these procedures, at a minimum, the following compounds shall be analyzed for and included in the calculations: Benzo[a]pyrene, Benz[a]anthracene, Benzo[b]fluoranthene, Benzo[k]fluoranthene, Chrysene, Dibenzo[a,h]anthracene, Indeno[1,2,3cd]pyrene. The department may require additional compounds from ~~the CalEPA list Table 708-2~~ to be included in the methodology should site testing data or information from other comparable sites or waste types indicate the additional compounds are potentially present at the site. *NOTE: Many of the ~~polycyclic aromatic hydrocarbons~~ carcinogenic PAHs on the CalEPA list in Table 708-2 are found primarily in air emissions from combustion sources and may not be present in the soil or water at contaminated sites. Users should consult with the department for information on the need to test for these additional compounds.*

WAC 173-340-900 Tables.

Table 708-2 (New Table)
**Toxicity Equivalency Factors for Chlorinated dibenzo-p-dioxins (CDD),
 Chlorinated Dibenzofurans (CDF) and Dioxin-Like Polychlorinated Biphenols (PCBs)**

Hazardous Substance	TEF (unitless) (1)
<u>Minimum Required cPAHs</u>	
benzo[a]pyrene	1
benzo[a]anthracene	0.1
benzo[b]fluoranthene	0.1
benzo[k]fluoranthene	0.1
chrysene	0.01
dibenz[a,h]anthracene	0.1
indeno[1,2,3-cd]pyrene	0.1
<u>Potential Additional cPAHs (2)</u>	
benzo(j)fluoranthene	0.1
dibenz[a,j]acridine	0.1
dibenz[a,h]acridine	0.1
7H-dibenzo[c,g]carbazole	1
dibenzo[a,e]pyrene	1
dibenzo[a,h]pyrene	10
dibenzo[a,i]pyrene	10
dibenzo[a,l]pyrene	10
5-methylchrysene	1
1-nitropyrene	0.1
4-nitropyrene	0.1
1,6-dinitropyrene	10
1,8-dinitropyrene	1
6-nitrochrysene	10
2-nitrofluorene	0.01
7,12-dimethylbenzanthracene ^a	10
3-methylcholanthrene ^a	1
5-nitroacenaphthene	0.01

(1) Source: Cal-EPA, 2005. Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II Technical Support Document for Describing Available Cancer Potency Factors. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. May 2005.

(2) May be required by Ecology under WAC 173-340-708(8)(e)

Draft Rule Revisions – PCB Mixtures (WAC 173-340-708(8)(f))

Ecology is also considering several rule revisions that are intended to clarify the policies and procedures for establishing cleanup levels for mixtures of polychlorinated biphenyls (PCBs), including the following:

- New language to clarify that PCB mixtures will be considered a single hazardous substance for purposes of establishing cleanup levels. This means a 1×10^{-6} cancer risk is applied to the mixture under Method B and a 1×10^{-5} cancer risk is applied to the mixture under Method C.
- Enabling language to allow the use the TEF methodology to evaluate PCB mixtures.
- If the TEF methodology is used, requires use of the toxicity equivalency factors for dioxin-like PCB congeners recommended by the World Health Organization. The TEF values for dioxin-like PCBs are included in a new table (Table 708-1).
- A description of the procedures for using the TEF methodology for purposes of calculating and/or evaluating compliance with cleanup levels and remediation levels.

The specific current proposed rule revisions are to add a **new provision** to WAC 173-340-708(8) as follows:

(f) The following procedures shall be used when calculating excess cancer risk and determining compliance with cleanup levels and remediation levels for mixtures of polychlorinated biphenyls (PCB):

(i) PCB mixtures shall be considered a single hazardous substance.

(ii) The total toxic equivalent concentration is a measure of the toxicity of a mixture of PCBs. The total toxic equivalent concentration may be calculated using either of the following methods unless the department determines that there is clear and convincing scientific data which demonstrates that the use of these methods is inappropriate::

(A) The PCB mixture is assumed to be equally potent and an appropriate carcinogenic potency factor provided for under WAC 173-340-708(8)(a) is applied to the entire mixture; or

(B) The toxicity equivalency factors in table 708-1 are used to convert the dioxin-like PCBs in the mixture to a total toxic equivalent concentration of 2,3,7,8 TCDD using the following process:

(I) Analyze a sample of the mixture or a sample from the medium of concern to determine the total PCB concentration and the concentration of each of the dioxin-like PCB congeners listed in Table 708-1;

(II) Multiply each dioxin-like PCB concentration in the sample by its corresponding toxicity equivalency factor in Table 708-1 to obtain a toxic equivalent concentration for each congener expressed in terms of 2,3,7,8 TCDD;

(III) Add the toxic equivalent concentrations of all of the dioxin-like PCBs to obtain a total toxic equivalent concentration of 2,3,7,8 TCDD for that sample expressed in terms of 2,3,7,8 TCDD;

(iii) The total toxic equivalent concentration derived under WAC 173-340-708(8)(f)(ii)(A) and (B) and the carcinogenic potency factor for 2,3,7,8 TCDD provided for under WAC 173-340-708(a) shall be used to calculate excess cancer risk and determine compliance with cleanup levels and remediation levels. When using the method in WAC 173-340-708(8)(f)(i)(B), the department may also require that the health risks posed by the non dioxin-like PCB congeners be assessed.

General Provisions

Ecology is also proposing to add a new provision to WAC 173-340-708(8) to specify that if TEFs are being used, the carcinogenic PAH-specific properties and dioxin/furan/PCB congener-specific properties be used when using modeling to predict cross-media impacts. This is consistent with the most recent recommendations made by EPA to the National Academy of Sciences/National Research Council (NAS/NRC, 2003).

The specific current proposed rule revisions are to add a new provision to WAC 173-340-708(8) as follows:

~~(f)(g)~~ When determining the concentrations of CDD, CDF, carcinogenic PAH, and PCB mixtures in one medium that are protective of another medium, the following procedures shall be used:

(i) When assuming the mixture is equally potent, use the properties of the index chemical (2,3,7,8 TCDD, benzo(a)pyrene or the PCB Aroclor) when modeling the behavior of these hazardous substances to determine the concentration in the receiving medium; or,

(ii) When using toxicity equivalency factors, use the congener and carcinogenic PAH-specific properties when modeling the behavior of these hazardous substances to determine the concentration in the receiving medium.

(iii) Once a concentration has been determined for the receiving medium (e.g., the fate and transport models in WAC 173-340-747 for the soil-to-ground water exposure pathway evaluation), the procedures in WAC 173-340-708(d), (e) and (f) shall then be used to calculate carcinogenic risk of the resulting concentrations and determine compliance with this chapter.

Other miscellaneous changes to WAC 173-340-708(8) including the following:

~~(f)(h)~~ In estimating a carcinogenic potency factor for a hazardous substance under (c) of this subsection, **or approving of the use of a toxicity equivalency factor other than that established under (d), (e) or (f) of this subsection,** the department shall, as appropriate, consult with the science advisory board, the department of health, and the United States Environmental Protection Agency and may, as appropriate, consult with other qualified persons. Scientific data supporting such a change shall be subject to the requirements under WAC 173-340-702 (14), (15) and (16). Once the department has established a carcinogenic potency factor **or an alternative toxicity equivalency factor** for a hazardous substance under this provision, the department is not required to consult again for the same hazardous substance.

~~(g)(i)~~ Where a carcinogenic potency factor other than that established under (a), ~~(d) (b)~~ and ~~(e)(c)~~ of this subsection **or a toxicity equivalency factor other than that established under (d), (e) and (f) of this subsection** is used to establish cleanup levels or remediation levels at individual sites, the department shall summarize the scientific rationale for the use of that value in the cleanup action plan. The department shall provide the opportunity for public review and comment on this value in accordance with the requirements of WAC 173-340-380 and 173-340-600.

Ecology is also proposing to revise the terminology for dioxins in Tables 749-2, 749-3 & 749-5 to make it internally consistent with Section 708.

Table 749-2 (In Part)
Priority Contaminants of Ecological Concern for Sites that Qualify for the Simplified Terrestrial Ecological Evaluation Procedure

Priority contaminant	Soil concentration (mg/kg)	
	Unrestricted land use ^b	Industrial or commercial site
OTHER CHLORINATED ORGANICS:		
Chlorinated dibenzofurans (total)	3E-06 mg/kg	3E-06 mg/kg
Chlorinated dibenzo-p-dioxins (total)	5E-06 mg/kg	5E-06 mg/kg
PCB mixtures (total)	2 mg/kg	2 mg/kg
OTHER NONCHLORINATED ORGANICS:		
Benzo(a)pyrene	30 mg/kg	300 mg/kg

Table 749-3 (In Part)
Ecological Indicator Soil Concentrations (mg/kg) for Protection of Terrestrial Plants and Animals

Hazardous Substance ^b	Plants ^c	Soil Biota ^d	Wildlife ^e
OTHER CHLORINATED ORGANICS:			
Chlorinated dibenzofurans (total)			2E-06
Chlorinated dibenzo-p-dioxins (total)			2E-06
PCB mixtures (total)	40		0.65
OTHER NONCHLORINATED ORGANICS			
Benzo(a)pyrene			12

Table 749-5 (in Part)
Default Values for Selected Hazardous Substances for use with the Wildlife Exposure Model in Table 749-4

Hazardous Substance	Toxicity Reference Value (mg/kg - d)				
	BAF _{Worm}	K _{Plant}	Shrew	Vole	Robin
OTHER CHLORINATED ORGANICS:					
Chlorinated dibenzofurans	48				1.0E-05
Chlorinated dibenzo-p-dioxins	48	0.005 ^b	2.2E-05	1.7E-05	1.4E-04
PCB mixtures	4.58	0.087 ^b	0.668	0.51	1.8
OTHER NONCHLORINATED ORGANICS:					
Benzo(a)pyrene	0.43	0.011	1.19	0.91	